

# EXHIBIT A

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April 11, 2008

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**VIA ELECTRONIC MAIL AND FEDERAL EXPRESS**

George B. Henderson, II, Esq.  
Assistant U.S. Attorney  
John Joseph Moakley U.S. Courthouse  
Suite 9200  
Boston, Massachusetts 02210

Re: United States ex. rel. Ven-A-Care of the Florida Keys, Inc.  
v. Dey, Inc., et al., Civil Action No. 05-11084-PBS

Dear Bunker:

Pursuant to Paragraph 13 of the Case Management Order entered in this action on June 22, 2007, please provide dates and witnesses for the following 30(b)(6) topics:

1. The investigation, preparation, and drafting of the following GAO reports, letters, and testimony (herein collectively referred to as the "GAO Prescription Drug Reports"):
  - (a) GAO-HRD-36, Programs to Control Prescription Drug Costs Under Medicare and Medicaid Should Be Strengthened (Dec. 31, 1980);
  - (b) HRD-92-110, Prescription Drugs: Companies Typically Charge More in the United States Than in Canada (September 30, 1992);
  - (c) GAO-RPT, "Outpatient Drug Costs and Reimbursement for Select Pharmacies in Illinois and Maryland (March, 1993);

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- (d) GAO-RPT, "Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom" (Letter Report, 1/12/1994, GAO/HEHS-94-29);
- (e) GAO-RPT, "Prescription Drugs - Spending Controls in Four European Countries" (GAO/HEHS-94-30, May 17, 1994);
- (f) GAO-RPT, "Medicare Drug and Nutrient Prices" (Letter from William Scanlon to Representative Pete Stark)" (GAO/HEHS-97-22R, Oct. 11, 1996);
- (g) GAO-RPT, "Drug Prices - Effects of Opening Federal Supply for Pharmaceuticals Are Uncertain" (GAO/HEHS-97-60, June 11, 1997);
- (h) GAO/HEHS-00-118, "Prescription Drugs – Expanding Access to Federal Prices Could Cause Other Price Changes" (Aug. 7, 2000);
- (i) GAO-01-1118, "Medicare-Payments for Covered Outpatient Drugs Exceed Providers' Costs" (Sept. 21, 2001);
- (j) GAO-01-1142T, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices" (Sept. 21, 2001);
- (k) GAO-02-531T, "Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices" (Mar. 14, 2002);
- (l) GAO-05-72, Medicare: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs (October 12, 2004);
- (m) GAO-05-836T, Medicaid: States' Efforts to Maximize Federal Reimbursements Highlight Need for Improved Federal Oversight (June 28, 2005);
- (n) GAO-05-855T, Medicaid Fraud and Abuse: CMS's Commitment to Helping States Safeguard Program Dollars Is Limited (June 28, 2005);

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- (o) GAO-05-779, Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004 (August 15, 2005);
- (p) GAO-06-69R, Medicaid: States' Payments for Outpatient Prescription Drugs (October 31, 2005);
- (q) GAO-06-971T, Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain (July 13, 2006);
- (r) GAO-07-329R, Medicaid Federal Upper Limits (December 22, 2006).

2. How and why the GAO made the decision to investigate and report on the topics and subjects contained in the GAO Prescription Drug Reports.

3. The substance of each of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC; AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.

4. The supporting data and evidence on which the GAO Prescription Drug Reports are based, including the working files.

5. The process by which the GAO gathered supporting data and evidence for the GAO Prescription Drug Reports.

6. All prior drafts and revisions of the GAO Prescription Drug Reports.

7. All comments received in response to the GAO Prescription Drug Reports.

8. The GAO's current understanding of the following terms used in the GAO Prescription Drug Reports: AWP; WAC; FUL; MAC; and AMP, and how the GAO's understanding has changed from 1980 to the present.

9. The basis in fact concerning the meaning of the following terms used in the GAO Prescription Drug Reports: AWP; WAC; FUL; MAC; and AMP.

10. The distribution of each of the GAO Prescription Drug Reports, including but not limited to the distribution to the United States' Congress, governmental agencies, and individual states.

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11. The identity of the individuals involved in the investigation, preparation, drafting and distribution of each of the GAO Prescription Drug Reports.
12. The GAO's communications with the United States Congress regarding each of the GAO Prescription Drug Reports.
13. The GAO's communications with other federal entities, including but not limited to the CMS/HCFA and the Department of Veterans Affairs regarding each of the GAO Prescription Drug Reports.
14. Congress, the GAO, and other governmental entities' responses and reactions to each of the GAO Prescription Drug Reports.
15. The actions taken by the GAO with respect to the issues relating to prescription drug pricing after the publication of each of the GAO Prescription Drug Reports.
16. The interplay and relationship between the GAO and the HHS Office of Inspector General ("OIG").
17. Communications between the GAO and the OIG regarding the subject matter of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC; AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.
18. Communications between the GAO and the public at large regarding the subject matter of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC; AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.
19. Communications between the GAO and individual states and state Medicaid programs regarding the subject matter of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC; AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.
20. Communications between the GAO and pharmaceutical manufacturers regarding the subject matter of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC;

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AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.

21. Communications between the GAO and Providers regarding the subject matter of the GAO Prescription Drug Reports, including but not limited to the following topics: prescription drug reimbursement methodologies; AWP; WAC; FUL; MAC; AMP; comparison of prescription drug pricing; generic pharmaceuticals; cost saving strategies and changes in reimbursement methodologies.

22. Any work done by the GAO, including but not limited to the GAO's work on the GAO Prescription Drug Reports, which touches on the Subject Drugs in the Dey action, albuterol, cromolyn, and ipatropium bromide, and the subject drugs in the Roxane action, *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.* No. 07-10248-PBS.

23. Data and knowledge gathered by the GAO through any means, including but not limited to data and knowledge obtained through the GAO's work on the GAO Prescription Drug Reports, regarding dispensing fees and the cost of distributing the Subject Drugs in the Dey action, albuterol, cromolyn, and ipatropium bromide, and the subject drugs in the Roxane action, *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.* No. 07-10248-PBS.

24. The investigation, preparation, drafting, approval and circulation of, and source of the information contained in, the Congressional Budget Office Report titled "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry," dated January 1996 letters, and testimony (herein referred to as the "1996 CBO Report").

25. The identity of the 224 drugs referenced in Box 2 on page 20 of the 1996 CBO Report, including the manufacturers of those drugs, and the investigation and analysis conducted giving rise to the assertions in that passage.

26. The identity of all federal government, state government and industry attendees of the November 27-28, 1990 Pharmacy Reform Tag Meeting and the positions advocated by each attendee regarding the contemplated disclosure by HCFA to the states of AMP data for the purposes of rebate calculation.

27. The identity of the commenters referenced in the Comment regarding "Confidentiality of Manufacturer Price Information" (60 Fed. Reg. 48475 (Sept. 19, 1995)) and the substance of those comments.

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28. The investigation, preparation, drafting, approval and circulation of the Response regarding "Confidentiality of Manufacturer Price Information" (60 Fed. Reg. 48475 (Sept. 19, 1995)) and the identity of the person(s) that drafted that Response.

29. The investigation, preparation, drafting, approval and circulation of the OIG report titled "Cost Containment of Medicaid HIV/AIDS Drug Expenditures" (OEI-05-99-00611 (July 2001)), including but not limited to the preparation and drafting of the chart on page 7 of that report titled "Chart 1: Pharmaceutical Industry."

30. The investigation, preparation, drafting, approval and circulation of the Medicaid Drug Rebate Operational Training Guide.

31. Any study drafted or reviewed by the United States regarding the transparency of pricing in the pharmaceutical industry and/or the effect complete pricing transparency in the pharmaceutical industry.

32. The extensions of time to intervene in the *qui tam* complaint filed by Ven-A-Care of the Florida Keys in the Southern District of Florida which were granted to the United States under 31 U.S.C. § 3730 (b)(3) of the False Claims Act, including but not limited to the reasons given for the delay, the number of extensions granted, the legal bases for those extensions, and the United States' conduct of its investigation into the allegations in the *qui tam* complaint.

33. The extensions of time to intervene in the *qui tam* complaint filed by Ven-A-Care of the Florida Keys in the District of Massachusetts which were granted to the United States under 31 U.S.C. § 3730 (b)(3) of the False Claims Act, including but not limited to the reasons given for the delay, the number of extensions granted, the legal bases for those extensions, and the United States' conduct of its investigation into the allegations in the *qui tam* complaint.

34. The allegedly false or fraudulent statements or actions made or taken by Dey that relate in any way to Your claims in the Complaint, including: false or fraudulent statements made or caused to be made by Dey and its agents; false or fraudulent claims filed by Dey and its agents; actions or statements that caused a false or fraudulent claim to be filed; and false or fraudulent price representations.

35. All instances of Dey "actively promoting" the spread as alleged in paragraph 1 of the complaint.

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36. The facts forming the basis for the allegation that “Dey knew that its false price reporting and marketing efforts would cause customers to submit claims for fraudulently inflated ... reimbursement” as alleged paragraph 4 of the complaint.

37. The facts in your possession relating to each and every instance in which Dey marketed the “spread” to any Provider as alleged in Paragraph 3 of the Complaint, including, for each such instance:

- (a) the employee of Dey who allegedly marketed the spread;
- (b) the Provider to whom the spread was marketed (and the individual employees of the Provider involved in the interaction);
- (c) the drug that was marketed;
- (d) the place and time of the alleged marketing;
- (e) the content of the alleged marketing (including the precise facts on which You base your assertion that the employee “marketed the spread”);
- (f) whether the Provider purchased or did not purchase the product; and
- (g) if applicable, all evidence that supports or refutes Your contention that the Provider purchased the product because of the spread between acquisition cost and reimbursement, as opposed to some other reason.

38. The facts and circumstances supporting the allegation in the complaint that Dey reported prices on an annual basis and that these prices were false as alleged in paragraph 34 of the complaint.

39. The facts and circumstances supporting the allegation in paragraph 43 of the complaint that state Medicaid Program relied on representations directly from manufacturers.

40. How and when the United States learned of the facts underlying the allegations in paragraphs 52 through 80 of the complaint.

41. For each of the Subject Drugs and for each quarter during the Relevant Claim period, the specific prices You contend Dey should have reported to Publishers or others and the basis for Your contention that Dey should have reported each of those prices to Medicare Part B or Medicaid.



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42. The dates, facts and circumstances describing when and how the Government learned of the fraud alleged in the complaint with respect to each of the Dey NDC numbers alleged in the complaint.

43. The basis for any contention that the price reported or represented by Dey for the Subject Drugs was used in determining reimbursement under Medicare Part B or Medicaid.

44. The damages You seek from Dey and the basis for that computation.

45. The amount by which the United States claims Dey was unjustly enriched and the basis for that computation.

46. The actual prices Dey should have reported in lieu of the allegedly fraudulent prices, and how those actual prices were determined.

47. Whether and to what extent CMS/HCFA, between 1991 to the present, was aware of the market prices for the Dey subject drugs and that Dey was allegedly "marketing the spread."

48. From 1991 to the present, any guidance, instruction, or requests communicated by CMS/HCFA to Dey regarding how to establish published and list prices.

49. From 1991 to the present, any guidance, instruction, or requests communicated by CMS/HCFA regarding marketing the spread.

50. The continued use of AWP as means for reimbursement in the Medicare Part D Program and Medicaid Program.

51. CMS's comments contained in the October 4, 2007 letter by Kerry Weems in response to the OIG's January, 2008 report entitled "Review of the Relationship between Medicare Part D Payments to Local Community Pharmacies and the Pharmacies' Drug Acquisition Costs."

52. CMS/HCFA's receipt of AMP information from Dey, its awareness of AMP and the use of such AMP.

53. CMS/HCFA's calculation of unit rebate amount ("URA") from AMP.

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54. Any comparisons done by CMS/HCFA of AMP or URA and any other price.

55. From 1990 to the present, all communications between CMS/HCFA and any State Medicaid Program concerning URA and/or AMP.

56. The Medicaid drug rebate program pursuant to 42 U.S.C. § 1396r-8 (the "Medicaid Rebate Program"), including, but not limited to: (a) the creation of the program; (b) the organization and history of the program; (c) how the program has been implemented and run; (d) the prices used in determining rebates; (e) the purpose of the program; (f) information provided by drug manufacturers; (g) negotiations with drug manufacturers; (h) determinations of rebate amounts; (i) invoices for rebates (and documents concerning such invoices) sent by or on behalf of You to Dey for the Dey Subject Drugs; (j) all correspondence between the State Medicaid Programs and CMS/HCFA concerning such rebates; (k) correspondence between Dey and CMS/HCFA; and (l) agreements entered into pursuant to the Medicaid Rebate Program.

57. The facts and circumstances underlying any advice provided or given by the general counsel of CMS/HCFA in which CMS/HCFA official or any official of any State Medicaid agency that CMS/HCFA was advised that they were not allowed to share AMP data with State Medicaid agencies and/or internally within CMS/HCFA.

58. The definition of Usual and Customary under the Medicare Program.

59. CMS/HCFA's definition of Usual and Customary under the Medicaid Program and the definition of Usual and Customary under each of the State Medicaid Programs at issue in this litigation.

60. Whether You contend that the Usual and Customary price submitted by any provider to Medicare or Medicaid for any Dey Subject Drug is false or fraudulent.

61. The drafting, approval, circulation, and publication of the Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, April 18, 2003 (hereinafter "OIG Compliance Guidelines"), including but not limited to (a) the individuals involved in the process; (b) when the OIG Compliance Guidelines were first proposed; and (c) comments and changes to the OIG Compliance Guidelines.

62. The definition of AWP as used in the OIG Compliance Guidelines that state: "Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C.

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1395u(o) Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.”

63. From 1991 to the present, communications between CMS/HCFA and the four DMERCs regarding the Dey Subject Drugs and/or the policies or practices for reimbursing and the policy of reimbursing inhalation and/or nebulizer drugs.

64. From 1991 to the present, all direct contact and communications between Dey representatives and the United States (including the Department of Justice) concerning the Subject Drugs, and the substance of those communications.

We reserve the right to supplement this letter with additional topics for any reason, including without limitation the motions pending in the Abbott action and ongoing nature or discovery in this action.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Neil Merkl', with a long horizontal flourish extending to the right.

Neil Merkl

cc: Laurie Oberembt, Esq.  
James J. Breen, Esq.